

AD \_\_\_\_\_

Award Number: DAMD17-03-1-0676

TITLE: Increasing Adherence to Follow-Up of Breast Abnormalities in Low-Income  
Korean American Women: A Randomized Controlled Trial

PRINCIPAL INVESTIGATOR: Annette E. Maxwell, M.D., Ph.D.

CONTRACTING ORGANIZATION: University of California at Los Angeles  
Los Angeles, CA 90024

REPORT DATE: September 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20060315 058

| REPORT DOCUMENTATION PAGE  |                  |                          |                            | Form Approved<br>OMB No. 0704-0188                       |   |
|--|------------------|--------------------------|----------------------------|--|---|
| Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.   |                  |                          |                            |  |   |
| 1. REPORT DATE (DD-MM-YYYY)<br>01-09-2005  |                  | 2. REPORT TYPE<br>Annual |                            | 3. DATES COVERED (From - To)<br>1 Sep 2004 - 31 Aug 2005 |   |
| 4. TITLE AND SUBTITLE<br>Increasing Adherence to Follow-Up of Breast Abnormalities in Low-Income Korean American Women: A Randomized Controlled Trial  |                  |                          |                            | 5a. CONTRACT NUMBER                                      |   |
|  |                  |                          |                            | 5b. GRANT NUMBER<br>DAMD17-03-1-0676                     |   |
|  |                  |                          |                            | 5c. PROGRAM ELEMENT NUMBER                               |   |
| 6. AUTHOR(S)<br>Annette E. Maxwell, M.D., Ph.D.<br><br>E-mail: amaxwell@ucla.edu   |                  |                          |                            | 5d. PROJECT NUMBER                                       |   |
|  |                  |                          |                            | 5e. TASK NUMBER  |   |
|  |                  |                          |                            | 5f. WORK UNIT NUMBER                                     |   |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)<br><br>University of California at Los Angeles<br>Los Angeles, CA 90024   |                  |                          |                            | 8. PERFORMING ORGANIZATION REPORT NUMBER                 |   |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)<br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012  |                  |                          |                            | 10. SPONSOR/MONITOR'S ACRONYM(S)                         |   |
|  |                  |                          |                            | 11. SPONSOR/MONITOR'S REPORT NUMBER(S)                   |   |
| 12. DISTRIBUTION / AVAILABILITY STATEMENT<br>Approved for Public Release; Distribution Unlimited   |                  |                          |                            |  |   |
| 13. SUPPLEMENTARY NOTES  |                  |                          |                            |  |   |
| 14. ABSTRACT<br><b>Purpose:</b> The purpose of this study is to design an intervention to assist Korean American (KA) women who require follow-up diagnostics after routine breast cancer screening who have missed their first follow-up appointment (at-risk women).<br><b>Scope:</b> We have conducted exploratory one-to-one interviews with health care providers who serve KA women with abnormal mammograms and with KA women who have been referred for follow-up diagnostics. We have designed an intervention that will utilize a peer navigator model and plan to test the intervention in a randomized trial among KA at risk women.<br><b>Major Findings:</b> We have identified a number of barriers that KA women who need a follow-up procedure encounter, including lack of provider interest, lack of time and resources on the part of providers and case managers, language barrier, lack of transportation, lack of understanding of the importance of follow-up, and fear of getting lost and being helpless at an unfamiliar and large health care facility. We found that the peer navigator should assist women by providing transportation and translation; providing support by answering questions and directing them to other available resources when appropriate; and serving as an advocate in the community to raise awareness and adherence. |                  |                          |                            |  |   |
| 15. SUBJECT TERMS<br>Adherence to follow-up of breast abnormalities, low-income Korean women, randomized controlled trial, peer counseling intervention  |                  |                          |                            |  |   |
| 16. SECURITY CLASSIFICATION OF:  |                  |                          | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES                                      | 19a. NAME OF RESPONSIBLE PERSON           |
| a. REPORT<br>U   | b. ABSTRACT<br>U | c. THIS PAGE<br>U        |                            |  | 19b. TELEPHONE NUMBER (include area code) |
|  |                  |                          | UU                         | 9  |   |

## Table of Contents

|                                   |   |
|-----------------------------------|---|
| Cover.....                        | 1 |
| SF 298.....                       | 2 |
| Table of Contents.....            | 3 |
| Introduction.....                 | 4 |
| Body.....                         | 4 |
| Key Research Accomplishments..... | 5 |
| Reportable Outcomes.....          | 5 |
| Conclusions.....                  | 6 |
| References.....                   | 6 |
| Appendices.....                   | 6 |

## **Introduction:**

The purpose of this study is to design an intervention to assist Korean American women who have been identified with a potential breast abnormality through the Breast Cancer Early Detection Program (BCEDP) and who have missed their first follow-up appointment (at-risk women). Intervention activities will include reminder phone calls or home visits by a trained peer counselor to explain the importance of follow-up procedures, emotional support, help with transportation to follow-up appointments, translations, organizing care for children or grandchildren during medical appointments, and other assistance to overcome barriers to follow-up identified during the initial phase of the study. We will collect extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities. We will conduct a follow-up survey to evaluate the effectiveness of the intervention in increasing adherence to follow-up procedures.

## **Body:**

The following activities listed in the Statement of Work have been completed:

### Task 1:

As part of the exploratory phase of the study, we had planned to review 30 charts in order to learn more about women who do and do not undergo diagnostic follow-up procedures in a timely manner. As explained in the previous progress report, we have dropped this plan. This change to the original Statement of Work was approved by the Grants Officer.

- a. We developed discussion guides for telephone interviews with health care providers and with Korean women for the exploratory phase of the study (Phase I). These discussion guides have been attached in the previous report.
- b. We have identified 15 women who received referral for follow-up procedures in the past 12 months and conducted telephone interviews with these women.
- c. We have identified 3 health care professionals through participating sites and conducted semi-structured telephone interviews.
- d. We have drafted the following intervention components and have translated them into Korean language:
  1. HIPAA Research Authorization
  2. Initial assessment and intervention form
  3. 6 month telephone follow-up survey
  4. Verbal Consent and Recruitment Script for Participation in the INTERVENTION PROTOCOL and Follow-up Survey with Korean American women (Phase II: Prospective Arm)

5. Verbal Re-Consent Script for Participation in the Follow-up Survey with Korean-American women (Phase II: Prospective Arm)
6. Verbal Consent and Recruitment Script for Participation in the Telephone Survey with Korean American women in the USUAL CARE GROUP (Phase II: Retrospective Arm)
7. Chart review patient letter

Above items and the protocol for the next phase of the study have been submitted to the UCLA IRB and DOD HSRRB and have been approved.

- g. We have established procedures to identify women who missed follow-up appointments on a daily basis.
- h. We have established randomization procedure.

Task 5:

- a. We have transcribed and translated audiotapes from semi-structured interviews in Phase I.
- b. We have analyzed data from Task 1. These findings have been summarized in Table A and have been attached.

**Key Research Accomplishments:**

Since our last report, we have completed the exploratory phase (Phase I) of our study. This included one-to-one in-depth interviews with 3 health care providers who serve Korean American women with abnormal mammograms and with 15 Korean American women who have been referred for follow-up diagnostics to examine barriers and predictors of adherence to follow-up of breast abnormalities and to identify culturally and linguistically sensitive methods of interventions to increase rate of adherence among Korean American women. Using interview findings, we have designed an intervention that will utilize a peer navigator model and plan to test the intervention in our next phase (Phase II), in a randomized trial among Korean American at-risk women who have missed their first appointment for a follow-up test after a routine annual breast cancer screening visit. We have submitted protocol and study materials for this phase to both the DOD and UCLA IRB and have received full approval from both institutions. In the next few weeks, we will hire peer navigators and train them before we implement our intervention in our 3 study sites, KHEIR, Koryo Health Foundation, and Moon Kim Clinic.

**Reportable Outcomes:**

Health care providers stated that Korean American women who need follow-up procedure(s) face language barriers, lack transportation, do not understand the importance of follow-up and the fact that procedures are paid through the Cancer Detection Program, and have the fear of getting lost and being helpless at an unfamiliar and large health care facility. Both providers and Korean American women stated that a peer navigator could

help women in overcoming these barriers to diagnostic follow-up and also serve as an advocate in the community to raise awareness and adherence. We will collect extensive process measures including number and type of intervention activities requested and delivered in order to estimate the feasibility for institutionalizing intervention activities. We will conduct chart reviews and a follow-up survey to evaluate the effectiveness of the intervention in increasing adherence to follow-up procedures.

We have attached a summary of findings from the exploratory phase of our study in the appendix (Table A). We have also presented our findings at the Conference of Hope Conference in Philadelphia in June 2005.

**Conclusions:**

Findings from the exploratory phase suggest that a peer navigator model will greatly facilitate adherence to follow-up of breast abnormalities by Korean American at-risk women who have missed their first appointment for a follow-up test after a routine annual breast cancer screening visit. We have therefore designed an intervention that will utilize a peer navigator model and plan to test this intervention in our next phase.

**References:**

N/A

**Appendices:**

1. Original Statement of Work
2. Summary of Phase I exploratory interview findings

## **Statement of Work**

### **Task 1: Setup and Formative Research (Months 01-06)**

- a. Develop chart review forms; develop discussion guides for semi-structured interviews (English and Korean, using standard translation procedures including back translations)
- b. Identify women who received a referral for follow-up procedures in the past 12 months from BCEDP logs. Conduct chart reviews (N=30) and telephone interviews (N=20) with these women (Angela Jo, Kim Young)
- c. Identify 5 health care professionals through participating sites and conduct semi-structured interviews (Maxwell, Jo, Young)
- d. Draft intervention components (strategies, scripts, materials) and assessment forms (intervention activity logs, needs assessment questions) - all materials in English and Korean language
- e. Hire and train 3 mature, English-Korean bilingual Korean American peer counselors
- f. Establish procedures to identify women who missed follow-up appointments on a daily basis
- g. Pretest intervention in 6-10 KA women, revise and finalize
- h. Establish randomization procedure

### **Task 2: Enroll subjects into randomized trial (Months 07-30)**

- a. Identify eligible subjects (N=253 during the 2 year recruitment), randomize into the study and administer verbal informed consent to intervention subjects (choice of English or Korean).

### **Task 3: Conduct Intervention (Months 07-33)**

1. Conduct telephone needs assessment and counseling for each newly enrolled intervention subject (N=86). Contact each intervention subject at least once every other week until completion of diagnostic follow-up/treatment. Offer intervention components as appropriate. Document all contacts, responses to needs assessment questions, intervention requests and activities.
1. Conduct alternative protocol for intervention subjects who cannot be reached by telephone.
2. After completion of the follow-up survey, provide intervention to women in the control group who did not complete follow-up procedures.

### **Task 4: Data Collection (Months 3-40)**

- a. Collect and compile log sheets from contacts with intervention subjects (process measures) into a data base (months 7-35)
- b. Develop (draft, translate, back translate, pretest, revise) follow-up survey based on the Adherence Model (months 3-12)

- c. Hire and train interviewer(s) to conduct follow-up survey (months 12-13)
- d. Conduct post-intervention survey with all subjects (N=160) 6 months after referral for diagnostic follow-up. Administer verbal consent prior to conducting survey to subjects in the control group (months 13-40)
- e. Conduct chart reviews for all subjects (N=160) 6 months after referral for diagnostic follow-up (months 13-40)

**Task 5: Data Management and Analysis (Months 1-42)**

- a. Transcribe and translate into English audiotapes from semi-structured interviews.
- b. Analyze qualitative and quantitative data from Task 1.  
For qualitative data analysis, summarize transcripts from semi-structured interviews, including key points and notable quotes (in English and Korean language) using standard procedures (Krueger 1994); compare and consolidate summaries prepared independently by two Korean speaking investigators (Drs. Jo and Kim); sort findings by the domains of the Adherence Model.  
For quantitative analysis, tabulate findings from semi-structured interviews, including specific needs expressed, services requested and barriers and concerns voiced about follow-up procedures. Tabulate findings from chart reviews by adherence status.
- c. Set up data entry programs and enter information from intervention log sheets, needs assessments, intervention requests and activities (process measures)
- d. Set up data entry program and enter information from 6 month follow-up survey
- e. Set up data entry program and enter information from chart reviews
- f. Data management and cleaning will be ongoing
- g. Data analysis, preparation of annual reports and manuscripts.



**Table A: Summary of Phase I exploratory interview findings**

|  | <b>Provider Interview Findings</b>   | <b>Patient Interview Findings</b>   |
|--|--|---|
| <b>Barriers</b>                          | <ul style="list-style-type: none"> <li>➤ Language barrier</li> <li>➤ Lack of transportation</li> <li>➤ Lack of knowledge of importance of follow-up</li> <li>➤ Fear of getting lost and being helpless at an unfamiliar and large health care facility</li> <li>➤ Unable to fill out paperwork by self</li> </ul>  | <ul style="list-style-type: none"> <li>➤ Language barrier</li> <li>➤ Lack of transportation</li> <li>➤ Fear of getting lost and being helpless</li> <li>➤ Unable to complete paperwork by self</li> <li>➤ Fear of getting reported to the authorities</li> <li>➤ Not understanding that the follow-up is free of charge to them</li> </ul>  |
| <b>Predictors</b>                        | <ul style="list-style-type: none"> <li>➤ Peer navigator could help in overcoming the above barriers</li> <li>➤ Speaking the English language</li> <li>➤ Having transportation</li> <li>➤ Having knowledge of the importance of breast cancer</li> <li>➤ Having knowledge of the importance of follow-up tests</li> </ul>   | <ul style="list-style-type: none"> <li>➤ Peer navigator could help in overcoming the above barriers</li> <li>➤ Speaking the English language</li> <li>➤ Having friend or family member accompany to follow-up visit(s)</li> <li>➤ Having clear and accurate understanding of breast cancer, screening tests, follow-up tests, and related issues.</li> </ul>  |
| <b>Suggested roles of peer navigator</b> | <ul style="list-style-type: none"> <li>➤ Assist with translation and transportation</li> <li>➤ Help with paperwork</li> <li>➤ Accompany to doctor visits</li> <li>➤ Educate patients on the importance of follow-up</li> <li>➤ Educate patients on the details of the CDP program (i.e. free of charge to enrollees, no risk of deportation)</li> <li>➤ Answer questions that patients may have</li> <li>➤ Provide emotional support</li> <li>➤ Advocate in the community for breast cancer</li> </ul> | <ul style="list-style-type: none"> <li>➤ Assist with translation and transportation</li> <li>➤ Help with paperwork</li> <li>➤ Accompany to doctor visits</li> <li>➤ Provide accurate information regarding breast cancer, screening tests, follow-up tests, and related issues.</li> <li>➤ Answer questions that they may have</li> <li>➤ Provide emotional support</li> <li>➤ Educate patients on the details of the CDP program (i.e. free of charge to enrollees, no risk of deportation)</li> </ul> |